REMARKS

Claims 1-104 are pending in the application. Claims 18-46, 83-99, 101 and 104 have been withdrawn from consideration. Claims 1-17, 47-82, 100, 102 and 103 have been rejected. No claims have been allowed.

Claims 16, 62 and 80 have been cancelled. Claims 1, 47 and 65 have been limited to transgenic plants having DNA encoding a cellulase selected from the group consisting of an endoglucanase gene, an exoglucanase gene, a dextranase gene, and a beta-glucosidase gene. Support for cellulase genes of these types are found at page 17, line 29 through page 18, line 14 in the specification. Claims 1, 47 and 65 have also been limited to transgenic plants having at least one DNA encoding a ligninase comprising a lignin peroxidase gene. Support for ligninase comprising a lignin peroxidase gene is found at page 21, line 28 through page 22, line 5 in the specification. Finally, Claims 1, 47 and 65 have been limited to transgenic plants wherein the signal peptide directs the cellulase and ligninase to a plastid or apoplast. Support for directing the cellulase to a plastid or apoplast is found in Table 2 of the specification. The signal peptide VSP targets the enzyme to the apoplast (Specification: Table 2, construct 5; page 44, lines 31-34). The signal peptides rbcS SP and SSU target the enzyme

to the chloroplast (Specification: Table 2, constructs 2-4; page 44, lines 11-17 and 24-30) which is a plastid. Claims which are directed towards other organelles have been cancelled or amended. Claims 11, 57 and 75 have been amended to delete references to conferous and deciduous trees.

Claim Rejections- 35 USC §112

1. Claims 1-17, 47-82, 100, 102 and 103 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

The claims have been limited to DNA encoding a cellulase selected from the group consisting of an endoglucanase gene, an exoglucanase gene, a dextranase gene, and a beta-glucosidase gene. The term "cellulase" is used in the specification as a generic term that includes endoglucanases such as the EI beta-1,4-endoglucanase precursor gene (*e1*) of Acidothermus cellulolyticus, exoglucanases such as the cellobiohydrolase gene (*cbh1*) of *Trichoderma reesei*, the dextranase gene of *Streptococcus salivarius* encoding the 1,6-alpha-glucanhydrolase gene, and the beta-glucosidase gene from *Actinomyces naeslundi*.

Endoglucanases randomly cleave cellulose chains into

smaller units. The specification discloses plasmid constructs having the endoglucanase cDNA of *A. cellulolyticus* (Table 1, constructs 1 and 3, page 36; Table 2, constructs 4-6, page 43 of the specification) and SEQ ID NO:4. Another endoglucanases are the E2 cellulase (EC 3.2.1.4) from *T. fusca* incorporated by reference from U.S. Patent No. 5,981,835 to Austin-Phillips, *et al.* The sequence for E2 is disclosed in Austin-Phillips, *et al.* as SEQ ID NO:1. Exoglucanases include cellobiohydrolases, which have the enzymatic function of liberating glucose dimers (cellobiose) from the ends of cellulose chains. The specification discloses plasmid constructs having the exoglucanase cDNA of *T. reesi* (Table 1, constructs 2 and 4, page 36; Table 2, constructs 1-3, page 43 of the specification) and SEQ ID NO:6. Another exoglucanase is the E3 cellulase (EC 3.2.1.91) from *T. fusca* incorporated by reference from U.S. Patent No. 5,981,835 to Austin-Phillips, *et al.* The sequence for E3 is disclosed in Austin-Phillips, *et al.* as SEQ ID NO:2. Glucanhydrolases liberate glucose monomers from the ends of cellulose chains. The specification discloses the dextranases gene of *Streptococcus salivarius*, SEQ ID NO:8. Beta-glucosidases liberate D-glucose from cellobiose dimers and

soluble cellodextrins. The specification discloses the beta-glucosidase gene from *Actinomyces naeslundi*, SEQ ID NO:10.

The claims have also been limited to DNA encoding a ligninase from *Phanerochaete chrysosporium*. The ligninases from the white-rot fungus *Phanerochaete chrysosporium* include lignin peroxidase (LIP). The specification discloses the *ckg4* ligninase cDNAs (Table 3, constructs 1 and 3, page 48; Table 4, constructs 1 and 3, page 50 of the specification) isolated from *Phanerochaete chrysosporium*, and SEQ ID NO:11. The specification also discloses the *ckg5* ligninase cDNAs (Table 3, constructs 2 and 4; Table 4, constructs 2 and 4) isolated from *Phanerochaete chrysosporium*, and SEQ ID NO:13. Enzymes with LIP activity are known by those skilled in the art to be glycosylated heme proteins (MW 38 to 46 kDa) in structure and are functionally dependent on hydrogen peroxide for activity and catalyze the oxidative cleavage of lignin polymer. Additionally, these ligninases share very high sequence homology. Comparison of the nucleotide sequences show a 71.5% homology between the CLG4 and CLG5 ligninases in the coding regions (de Boer *et al.* Gene, 1987, vol. 60, pp. 93-102: page 100, column 2). A

comparison of the amino acid sequences of the two ligninases shows a very high percentage of homology (68.5%) between the two ligninases (de Boer *et al.*: page 100, column 1, last paragraph). According to M.P.E.P. 2163, a "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus (*See, e.g., In re Rasmussen*, 650 F.2d 1212 at 1214, 211 USPQ 323 at 326-27). The high homology between the nucleotide and amino acid sequences of the ligninases shows that a substantial variation within this genus does not exist. Therefore, the ligninases disclosed in the specification adequately supports the claimed genus.

M.P.E.P. 2163 II A. 3. (a)(ii) states that for each claim drawn to a genus, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by

functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The amended claims 1, 47 and 65 which are drawn to a genus have met the written description requirements by disclosing a combination of both the enzymatic function and the chemical structure as set out in the disclosed sequences. In light of these amendments, it is believed that the claimed subject matter is described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Reconsideration of the rejection is requested.

2. Claims 1-17, 47-82, 100, 102 and 103 were rejected under 35 U.S.C. §112, first paragraph. It is stated in the rejection that the specification, while enabling for a transformed herbaceous plant comprising a DNA encoding a cellulase and a ligninase operably linked to a plastid targeting DNA, does not reasonably provide enablement for a woody plant so transformed or for a transformed plant

comprising a DNA encoding a cellulase and a ligninase operably linked to a DNA for targeting to any organelle.

According to M.P.E.P. 2164.01(a), there are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: the breadth of the claims; the nature of the invention; the state of the prior art; the level of one of ordinary skill; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples; and the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). The claims have been amended to limit the targeting of the cellulase and the ligninase to a apoplast or a plastid. The signal peptide VSP targets the enzyme to the apoplast (Specification: Table 2, construct 5; page 44, lines 31-34). The signal peptides rbcS SP and SSU target the enzyme to the chloroplast (Specification: Table 2, constructs 2-4; page 44, lines 11-17 and 24-30) which is a plastid. Considering the amount of guidance for the construction of specific plasmids which enable one skilled

in the art to make and/or use the invention and the level of skill of those in the art, it would not require undue experimentation by one skilled in the art to make and/or use the invention targeted to an apoplast or a plastid such as the chloroplast.

As regards to the woody plants, the claims have been amended to remove references to woody plants such as coniferous and deciduous trees, while still claiming herbaceous plants. In light of these amendments, it is believed that the specification enables a person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with the claims. Reconsideration of the rejection is requested

Claim Rejections- 35 USC §103

3. Claim 1-17, 47-82, 100, 102 and 103 were rejected under 35 U.S.C. §103(a) as being unpatentable over Himmel *et al.* (U.S. Patent No. 6,013,860), in view of Crawford *et al.* (U.S. Patent No. 5,200,338), and in further view of de Boer *et al.* (Gene, 1987, vol. 60, pp. 93-102), and Applicants admissions.

Himmel *et al.* teach engineered plant cells having a

polysaccharide (cellulose) hydrolyzing enzyme integrated into the plant cell nuclear genome, with the enzyme being targeted to a cellular organelle.

Crawford *et al.* teach a lignin peroxidase enzyme obtained from a bacterial source which is capable of degrading the lignin of lignocellulose. Crawford *et al.* also teach removing lignin from lignocellulose in order to degrade cellulose to allow for the efficient use of cellulosic material.

De Boer *et al.* teach lignin peroxidase (LIP) genes *ckg4* (H2) and *ckg5* (H10), however de Boer *et al.* does not teach engineered plants having genes *ckg4* (H2) and *ckg5* (H10). Additionally, enzymatic methods of converting lignocellulose in a plant material to fermentable sugars, Genebank accession number X07515, and the *bar* gene were all known in the art as stated in the Applicant's specification.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a

reasonable expectation of success. Finally, the prior art reference, or references when combined, must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). None of the prior art references, taken alone or in combination, show or suggest all of the claim limitations which include a transgenic plant comprising at least one DNA encoding a cellulase and at least one DNA encoding a ligninase. Also, there is no suggestion or motivation to modify the reference or to combine reference teachings to provide a transgenic plant comprising a cellulase and a ligninase. Therefore, a *prima facie* case of obviousness has not been established. In light of these amendments, the Claims are patentable over the prior art device. Reconsideration of the rejection is requested.

The cited references do not teach all of the elements of the present invention. Therefore, in light of the above, it is now believed that Claims 1-15, 17, 47-61, 63-79, 81-82, 100, 102 and 103 are patentable and in condition suitable for allowance. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Enclosed are the required drawings.

Respectfully submitted,

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